Section 12
510(K) SUMMARY

APR 2 4 2013

SPONSOR:

Volcano Corporation
2870 Kilgore Road.
Rancho Cordova, CA 95670

CONTACT/SUBMITTER:

Lisa M. Quaglia
Senior Director, Regulatory Affairs
Volcano Corporation
1 Fortune Drive
Billerica, MA 01821
Tel: (978) 439-3586

DATE OF SUBMISSION:

September 13, 2012

DEVICE:

Volcano PreView® Forward-Looking IVUS Catheter and Laptop System

Trade Name:

Volcano PreView® Forward-Looking IVUS Catheter and Laptop System

Common Name:

Ultrasound Catheter/Catheter, Ultrasound, Intravascular; Percutaneous Catheter

Classification:

21 CFR Part 870.1250
Class II Device

PREDICATE DEVICE:

Volcano Revolution® Catheter (K080891)
Volcano s5/s5i Imaging System (K113486)
Avinger Wildcat Catheter with Juicebox (K111704)

DEVICE DESCRIPTION:

The PreView® Forward-Looking IVUS Catheter and Laptop System is an IVUS catheter with stand-alone laptop imaging system. The PreView® Catheter is a single use disposable device with a disposable single use motor for rotation of the catheter. The catheter is 135cm in length and connects to a PIM (Patient Interface Module) which contains the electronics. The PIM translates the echo data and sends it to the laptop for display on the computer screen.

INTENDED USE:

The PreView® Forward-Looking IVUS Catheter and Laptop System is indicated for use to facilitate the intraluminal placement of guidewires in the peripheral vasculature prior to further percutaneous intervention and

to support guidewires in accessing discrete regions of the peripheral vasculature, to assess vessel morphology, assess the position of the catheter tip within the vessel lumen, and to facilitate placement and exchanges of guidewires and other interventional devices compatible with 0.014" guidewire lumens. The PreView® Forward- Looking IVUS Catheter is designed as an adjunct to conventional angiographic procedures to provide a forward-looking image of the vessel lumen and wall structures.

The PreView® Forward-Looking IVUS Catheter and Laptop System is not indicated for use for imaging with the exposed rotating tip inside a stent. This device is not indicated for use in coronary or cerebral vessels.

COMPARISON OF CHARACTERISTICS:

The proposed device is substantially equivalent to currently marketed devices. The devices are support catheters consisting of a catheter shaft and hub and/or IVUS catheters consisting of a transducer and associated imaging system. All devices provide motorized rotation of the catheter. The proposed device is offered in a single catheter size and provides for a disposable motor for rotation of the catheter.

PERFORMANCE DATA:

Non-clinical device testing was conducted to confirm the performance of the device. Bench testing was conducted against known standards, product specification, or against the predicate device and evaluated the following:

- Dimensional Verification
- NURD (Non-Uniform Rotational Distortion)
- Simulated Use Performance Testing (Product Performance)
- Tip Tensile Testing
- Torque Strength Test (Torsional Strength)
- Particulate Evaluation
- Flexibility and Kink Test
- Buckling and Deflection
- Prep and Flush (Leak Testing)
- Image Assessment (Usability Testing)
- Acoustic Power Output Testing

Biocompatibility testing was conducted on the device and the following tests were successfully completed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity
- ASTM Hemolysis
- C3a Complement Activation
- SC5-b Complement Activation
- Material Mediated Pyrogens
- Partial Thromboplastin Time
- *In vivo* Thromboresistance

A GLP animal safety study was also completed to ensure the use of the device does not result in any untoward consequences. Completion of these tests concluded the PreView® Forward-Looking IVUS Catheter and Laptop System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2013

Volcano Corporation
Lisa M. Quaglia
Senior Director, Regulatory Affairs
1 Fortune Drive
Billerica, MA 01821

Re: K122826
Trade/Device Name: PreView Forward-Looking IVUS Catheter and Laptop System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, OBJ
Dated: September 13, 2012
Received: September 14, 2012

Dear Ms. Quaglia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)

Device Name PreView® Forward-Looking IVUS Catheter and Laptop System

Indications for Use The PreView® Forward-Looking IVUS Catheter and Laptop System is indicated for use to facilitate the intraluminal placement of guidewires in the peripheral vasculature prior to further percutaneous intervention and to support guidewires in accessing discrete regions of the peripheral vasculature, to assess vessel morphology, assess the position of the catheter tip within the vessel lumen, and to facilitate placement and exchanges of guidewires and other interventional devices compatible with 0.014" guidewire lumens. The PreView® Forward-Looking IVUS Catheter is designed as an adjunct to conventional angiographic procedures to provide a forward-looking image of the vessel lumen and wall structures.

The PreView® Forward-Looking IVUS Catheter and Laptop System is not indicated for use for imaging with the exposed rotating tip inside a stent. This device is not indicated for use in coronary or cerebral vessels.

Prescription Use ___X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2013.04.24 16:03:19
-04'00'